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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/634,049	08/04/2003	Jose Luis Francese	MED-015	5515
36822 7590 09/19/2007 GORDON & JACOBSON, P.C. 60 LONG RIDGE ROAD SUITE 407 STAMFORD, CT 06902			EXAMINER NGUYEN, TUAN VAN	
			ART UNIT 3731	PAPER NUMBER
			MAIL DATE 09/19/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/634,049	Applicant(s) FRANCESE ET AL.	
	Examiner Tuan V. Nguyen	Art Unit 3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 July 2007.
 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 4-32 is/are pending in the application.
 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
 5) ☐ Claim(s) _____ is/are allowed.
 6) ☒ Claim(s) 1 and 4-32 is/are rejected.
 7) ☐ Claim(s) _____ is/are objected to.
 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
 10) ☒ The drawing(s) filed on 04 August 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

1. Applicant's arguments filed on July 25, 2007 with respect to claim 19 have been fully considered and persuasive, therefore, the finality in previous Office Action is hereby withdraw.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. **Claims 1-9, 13-15 and 17 are rejected under 35 U.S.C. 102(b) as being anticipated by Aboul-Hosn (U.S. 6,228,063).**
4. Referring to **claims 1-9, 13-15 and 17**, Aboul-Hosn discloses (see Figs. 2-5) an surgical port device 10 for insertion through a body wall, comprising: a cylindrical elongated member 12, which made of polymer of stainless steel, or port body 12 including a tubular section having a distal 14 end and a flexible flange 22 disposed at said distal end; a retention member 80 that is slidably mated along said tubular section such that a distance between said retention member and said flexible flange can be adjusted, whereby said retention member and said flexible flange cooperate to clamp portions of the body wall 8 disposed therebetween and thus

effectively clamp said port body in place; flexible flange 22, that made of silicone, is adapted to reduce in diameter when said port body passes through a narrow opening in the body wall (see Fig. 2A) and said flexible flange 22 has a frusto-conical shape with a proximally-concave outer surface and the flange includes an annular projection that projects radially outward (see Fig. 5, the hidden line) wherein the projection is mating with the obturator 77 (see Fig. 3); obturator 77 having a rod-like section 75, tip 74, and handle 73 (see Fig. 2B); and a valve assembly 47 at the proximal end of cylindrical member 12 (see col. 4, line 12 to col. 6, line 45). Here it is noted that silicone material is a hydrophobic material. Extrinsic evidence, U.S. Patent No. 3,983,879 issued to Todd discloses silicone is a hydrophobic material (see col. 2, lines 43-45).

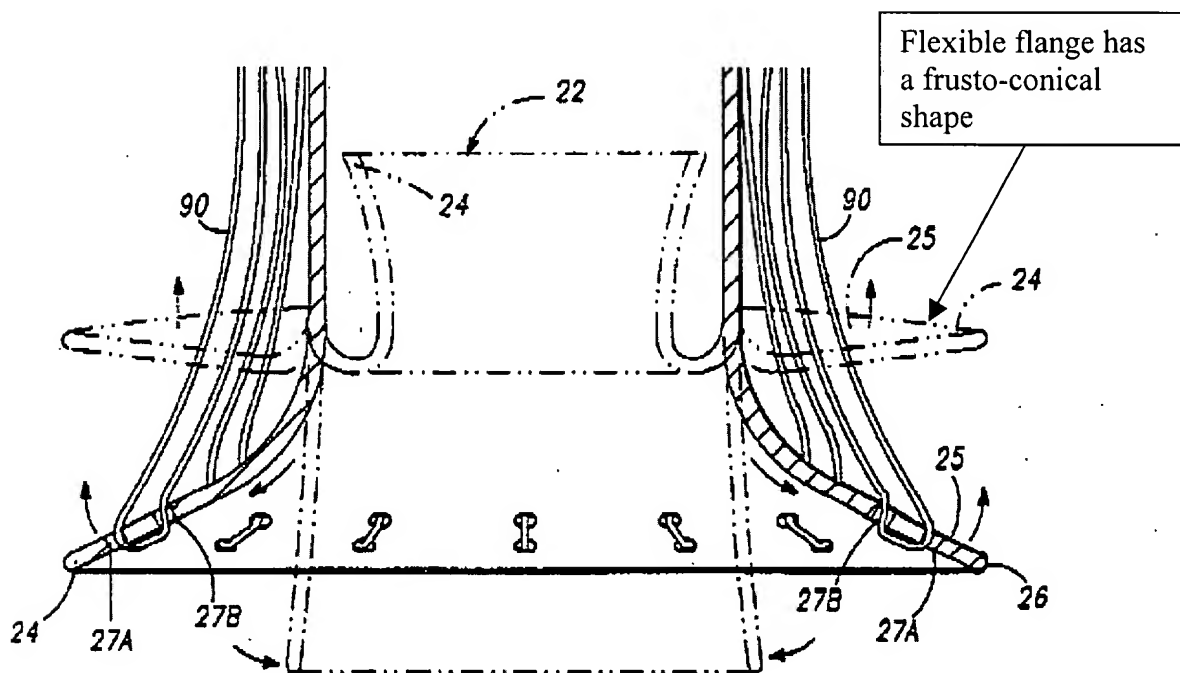


FIG. -5

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5. **Claims 19, 21, 23 are rejected under 35 U.S.C. 102(a) as being anticipated by Hogendijk et al. (U.S. 6,537,299).**
6. Hogendijk discloses a hemostasis device 10"" (see Fig. 18 and col. 20, line 27-68) comprising: a port body, that rod 12"" inserted into, including a tubular section, that rod 12"" inserted into, having a distal end 24"" and a flange, wherein the flange having a frusto-conical shape with a proximal-concave outer surface and also having an rim 19"" or annular projection that projects-radially outward from said outer surface.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action
 - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.
8. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:
 1. Determining the scope and contents of the prior art.
 2. Ascertaining the differences between the prior art and the claims at issue.
 3. Resolving the level of ordinary skill in the pertinent art.
 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

9. **Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Aboul-Hosn in view of Freitas et al. (U.S. 5,330,497).**

10. Referring to claim 10, Aboul-Hosn discloses the invention substantially as claimed except for the cylindrical elongated member 12 has plurality of grooves on the outer surface that mating with the retention member wherein the grooves resists the retention member sliding in a proximal direction. Freitas discloses (see Figs 8, 9, and 10) a locking trocar sleeve having retention member 72 and the cylindrical elongated member 170 has plurality of grooves on the outer surface that mating with the retention member wherein the grooves resists the retention member sliding in a proximal direction (see col. 7, lines 9-45). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made by the applicant to use the retention design, as disclosed by Freitas, to incorporate into the device, as disclosed by Aboul-Hosn because this will provide another failsafe feature beside suturing.

11. **Claims 11 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Aboul-Hosn in view of Loeffler (U.S. 2,064,435).**

12. Referring to claims 11 and 12, Aboul-Hosn discloses the invention substantially as claimed except for the tubular member having at least one window therein. Loeffler discloses a technique for reinforcement of a molded article wherein the reinforcement having plurality of holes for facilitate the flow of molding composition through (see page 1, lines 42-50). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made by the applicant to use

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the molding technique, as disclosed by Loeffler, to incorporate into the device, as disclosed by Aboul-Hosn to gain the advantages as suggested by Loeffler.

13. **Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over Aboul-Hosn in view of Shikhman et al. (U.S. 5,423,796).**

14. Referring to claim 16, Aboul-Hosn discloses the invention substantially as claimed except for a side port in fluid communication with said passage of the cylindrical elongated member. Shikhman discloses (see Fig. 1) a trocar system having side port 60 wherein the port 60 in fluid communication with the central passage of the trocar sleeve 24 for the purpose of insufflation and desufflation (see col. 5, lines 1-5) Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made by the applicant to add the side port, as disclosed by Shikhman, to incorporate into the device, as disclosed by Aboul-Hosn to gain the advantages of insufflation and desufflation as suggested by Shikhman. Here it is noted that side port for insufflation and desufflation in a trocar system is old and well known in the art.

15. **Claims 1-9, 13-24, 28-30 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Aboul-Hosn (US 6,814,713) in view of Hogendijk et al. (U.S. 6,537,299).**

16. Referring to claims 1-9, 13-24, 28-30 and 32, Aboul-Hosn discloses (see Figs. 1-4) a surgical port device for introducing into an organ disposed in chest cavity such as heart or vessel and performing minimal invasive surgery comprising: a

cylindrical elongated member 14, which made of polymer of stainless steel, or port body 14 including a tubular section having a distal end and a flexible flange 26 disposed at said distal end; a retention member 80 (see col. 3, lines 30-35 and Fig. 2-5 of U.S. Patent No. 6,228,063 issued to Aboul) that is slidably mated along said tubular section such that a distance between said retention member and said flexible flange can be adjusted, whereby said retention member and said flexible flange cooperate to clamp portions of the body wall 8 disposed therebetween and thus effectively clamp said port body in place; flexible flange 26, that made of silicone, is adapted to reduce in diameter when said port body passes through a narrow opening in the body wall (see Fig. 2A) and said flexible flange 26 has a conical shape with a proximally-concave outer surface and the flange includes an annular projection that projects radially outward, wherein the projection is mating with the obturator 24 (see Figs. 2); obturator 24 having a rod-like section, tip 24, and handle (see Figs. 1 and 4); and a valve assembly 18 at the proximal end of cylindrical member 24 (see col. 3, line 26 to col. 5, line 5). Here it is noted that silicone material is a hydrophobic material. Extrinsic evidence, U.S. Patent No. 3,983,879 issued to Todd discloses silicone is a hydrophobic material (see col. 2, lines 43-45). Aboul-Hosn discloses the invention substantially as claimed except for the flange 26 having a frusto-conical shape with a proximally-concave outer surface and also having an annular projection that projects radially outward from the said outer surface.

17. Referring to claims **1-9, 13-24, 28-30 and 32**, however, Hogendijk discloses (see Fig. 18 and col. 20, lines 27-68) a hemostasis device 10 comprising: a port body, that rod 12 inserted into, including a tubular section, that rod 12 inserted into, having a distal end 24 and a flange, wherein the flange having a frusto-conical shape with a proximal-concave outer surface and also having a rim 19 or annular projection that projects-radially outward from said outer surface to form a channel 72 to form a positive sealing between the tissue and the device thereby preventing the leakage of bodily fluid. Therefore, it would have been obvious to one of ordinary skill in the art to incorporate the rim 19 or annular projection that projects-radially outward from said outer surface to form a channel 72 to form a positive sealing between the tissue and the device as disclosed by Hogendijk into the flange 26 of Aboul-Hosn to gain the advantage of preventing the leakage of bodily fluid from the vessel or the heart as suggested by Hogendijk.
18. **Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Aboul-Hosn (US 6,814,713) in view of Hogendijk further in view of Freitas et al. (U.S. 5,330,497).**
19. Referring to claim 10, the modified device of Aboul-Hosn discloses the invention substantially as claimed except for the cylindrical elongated member 12 has plurality of grooves on the outer surface that mating with the retention member wherein the grooves resists the retention member sliding in a proximal direction. Freitas discloses (see Figs 8, 9, and 10) a locking trocar sleeve having retention member 72 and the cylindrical elongated member 170 has plurality of grooves on

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the outer surface that mating with the retention member wherein the grooves resists the retention member sliding in a proximal direction (see col. 7, lines 9-45). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made by the applicant to use the retention design, as disclosed by Freitas, to incorporate into the device, as disclosed by Aboul-Hosn because this will provide another failsafe feature beside suturing.

20. **Claims 11-12 and 26-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Aboul-Hosn (US 6,814,713) in view of Hogendijk further in view of Loeffler (U.S. 2,064,435).**
21. Referring to claims 11-12 and 26-27, the modified device of Aboul-Hosn discloses the invention substantially as claimed except for the tubular member having at least one window therein. Loeffler discloses a technique for reinforcement of a molded article wherein the reinforcement having plurality of holes for facilitate the flow of molding composition through (see page 1, lines 42-50). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made by the applicant to use the molding technique, as disclosed by Loeffler, to incorporate into the device, as disclosed by Aboul-Hosn to gain the advantages as suggested by Loeffler.
22. **Claims 16 and 31 rejected under 35 U.S.C. 103(a) as being unpatentable over Aboul-Hosn (US 6,814,713) in view of Hogendijk further in view of Shikhman et al. (U.S. 5,423,796).**

23. Referring to claims 16 and 31, the modified device of Aboul-Hosn discloses the invention substantially as claimed except for a side port in fluid communication with said passage of the cylindrical elongated member. However, Shikhman discloses (see Fig. 1) a trocar system having side port 60 wherein the port 60 in fluid communication with the central passage of the trocar sleeve 24 for the purpose of insufflation and desufflation (see col. 5, lines 1-5) Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made by the applicant to add the side port, wherein the side port is communicated with the passage as disclosed by Shikhman, to incorporate into the modified device, as disclosed by Aboul-Hosn/Hogendijk to gain the advantages of insufflation and desufflation as suggested by Shikhman.
24. **Claim 25 is rejected under 35 U.S.C. 103(a) as being unpatentable over Aboul-Hosn (US 6,814,713) in view of Hogendijk et al. (U.S. 6,537,299) further in view of Freitas et al. (U.S. 5,330,497).**
25. The modified device Aboul-Hosn discloses the invention substantially as claimed except for the cylindrical elongated member 12 has plurality of grooves on the outer surface that mating with the retention member wherein the grooves resists the retention member sliding in a proximal direction. Freitas discloses (see Figs 8, 9, and 10) a locking trocar sleeve having retention member 72 and the cylindrical elongated member 170 has plurality of grooves on the outer surface that mating with the retention member wherein the grooves resists the retention member sliding in a proximal direction (see col. 7, lines 9-45). Therefore, it would have

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been obvious to one of ordinary skill in the art at the time the invention was made by the applicant to use the retention design, as disclosed by Freitas, to incorporate into the device, as disclosed by Aboul-Hosn because this will provide another failsafe feature beside suturing.

Conclusion


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tuan V. Nguyen whose telephone number is 571-272-5962. The examiner can normally be reached on M-F: 9:00 AM - 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anh Tuan Nguyen can be reached on 571-272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Tuan V. Nguyen

September 14, 2007


ANH TUAN T. NGUYEN
SUPERVISORY PATENT EXAMINER
